UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

J M SMITH CORPORATION d/b/a, SMITH DRUG COMPANY, on behalf of itself and all others similarly situated,

Plaintiff,

v.

ACTAVIS, PLC, FOREST LABORATORIES, LLC, MERZ GMBH & CO. KGAA, MERZ PHARMA GMBH & CO. KGAA and MERZ PHARMACEUTICALS GMBH

Defendants.

No. 15-cv-7488-CM

REDACTED

[CORRECTED*] DIRECT PURCHASER PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANTS FOREST AND MERZ'S MOTION TO DISMISS INDIRECT PURCHASER PLAINTIFFS' CLASS ACTION COMPLAINT AND DIRECT PURCHASER PLAINTIFFS' FIRST AMENDED CLASS ACTION COMPLAINT

* Corrections are to typographical errors only.

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I. INTRODUCTION

Plaintiffs[1] allege that Defendants[2] engaged in a comprehensive and anticompetitive scheme to forestall generic competition in the market for memantine hydrochloride that Defendants sold under the brand name Namenda IR. The scheme centered on Defendants' plan to switch the market from Namenda IR to Namenda XR before generic versions of Namenda IR could enter the market. The Second Circuit has already held that there is a "substantial likelihood" that Defendants' "product hop" violated Section 2 of the Sherman Act, 15 U.S.C. §2. *New York v. Actavis PLC*, 787 F.3d 638, 642 (2d Cir. 2015) ("*Namenda II*").

Critical to the scheme's success was the need to delay generics from coming to market before the product hop could be effectuated. Defendants accomplished this by entering into litigation settlements with multiple generic drug companies that challenged the validity of U.S. Patent No. 5,061,703 (the "'703 patent" or the "patent") purportedly protecting Namenda IR. Pursuant to these settlements, the generics agreed not to compete with Defendants and to stay off the market *even after the '703 patent expired on April 11, 2015*.

Specifically, Plaintiffs allege that the licenses Defendants conveyed to generics as part of the settlements were unlawful on their face, because, as the Supreme Court recently reaffirmed, a patentee cannot extend its patent beyond the patent's term. *Kimble v. Marvel Entm't, LLC*, 135 S. Ct. 2401, 2407 (2015); *Brulotte v. Thys Co.*, 379 U.S. 29, 30, 33 (1964). Consequently, the express agreements between Defendants and the generics to not compete after the patent expired

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[1] "Plaintiffs" refers to the direct purchaser plaintiffs, including the J M Smith Corp., d/b/a Smith Drug Company and Rochester Drug Co-Operative, Inc.

[2] "Defendants" refers to Forest Laboratories, LLC ("Forest"), Actavis, PLC, Merz GMBH & Co. KGAA, Merz Pharma GMBH & Co. KGAA, and Merz Pharmaceuticals GMBH (collectively "Merz").

can only be viewed as naked restraints of trade typically condemned as *per se* violations of the Sherman Act. *See, e.g., Palmer v. BRG of Ga., Inc.*, 498 U.S. 46, 49-50 (1990) (per curiam). Defendants respond that they had a pediatric exclusivity, obtained on June 18, 2014 (*years after* the agreements), which they say extended the '703 patent term by six months. But pediatric exclusivity is not a patent term extension. *See, e.g., Altana Pharma AG v. Teva Pharms. USA, Inc.*, 2012 U.S. Dist. LEXIS 79166, at *9 (D.N.J. June 7, 2012).[3] Further, in the circumstances of this case, pediatric exclusivity was not a bar to the generics coming to market. To obtain pediatric exclusivity that would apply against a generic company that had filed a Paragraph IV certification, Defendants would have had to obtain a "court determin[ation] that the patent is valid and would be infringed." 21 U.S.C. § 355a(c)(1)(B)(II). Not only did Defendants not obtain such a court determination, they affirmatively disabled a court from ever being able to do so, in order to (1) preserve a "bottleneck" preventing subsequent patent challenges, and (2) avoid risking a decision that would end their patent monopoly.

Moreover, because at least seven of the generic companies that filed Paragraph IV ANDA applications with the FDA to market a generic version of Namenda before the '703 patent expired *had already received final approval from the FDA*,[4] the later grant of pediatric exclusivity could not have prevented or delayed them from coming to market. The fact that these seven ANDA filers had final approval to launch generic Namenda IR, which the FDA never rescinded – even during Defendants' purported pediatric exclusivity period, also undermines Defendants' argument that the FDA cannot grant final approval to an ANDA filer when the brand has a potential pediatric exclusivity.

[3] Rather, it is a statutory directive to the FDA to extend the period in which an ANDA may not be approved, as long as the statutory requirements are met. 21 U.S.C. § 355a(c)(1)(B)(II).

[4] First Amended Class Action Complaint ¶ 133, ECF No. 29 ("Compl.").

Defendants' scheme, of course required them to induce the generic companies that filed Paragraph IV applications and were seeking to market generic versions of Namenda IR *before* the patent expired to abandon their patent challenges. Plaintiffs' complaint plausibly alleges that Forest paid its would-be generic competitors money, and in exchange those would-be competitors agreed to stay off the market until January 2015, even though they had FDA approval and could have launched well before then. Compl. ¶¶ 7, 114-116, 132-133; Memorandum in Support of Defendants Forest and Merz's Motion to Dismiss Indirect Purchaser Plaintiffs' Class Action Complaint and Direct Purchaser Plaintiffs' First Amended Class Action Complaint at 40 n.25, ECF No. 57 ("Defs.' Br.") (generics could have entered in 2011 or earlier if they prevailed in the patent cases). These pay-for-delay agreements are unlawful under *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013). Plaintiffs allege payments of "many millions of dollars" that induced the generics to quit their patent challenges. Compl. ¶¶ 7, 119, 246. Whether these reverse payments are "large and unjustified" under *Actavis* is an issue of fact inappropriate for disposition at the pleading stage. *Actavis*, 133 S. Ct. at 2236 ("[T]hat possibility does not justify dismissing the FTC's complaint").

Plaintiffs have also plausibly alleged that Forest brokered a conspiracy between and among its generic competitors (and itself) to delay generic competition for Namenda IR. Each of the generic ANDA applicants – especially those that were "first filers" and entitled to shared 180-day marketing exclusivity – would not have agreed to delay coming to market without the assurance that its competitors would do the same. Plaintiffs allege that Defendants brokered a common agreement among all of the generics to stay off the market until the exact same delayed entry date through contingent entry clauses that permitted a settling generic to enter the market earlier if any other generic refused to join the conspiracy and was able to enter the market earlier.

The Supreme Court, the Seventh Circuit, this Circuit and other district courts have recognized that, at a minimum, allegations of analytically identical conduct state a claim under § 1 of the Sherman Act1 of the Sherman Act (15 U.S.C. § 1). *See United States v. Masonite Corp.*, 316 U.S. 265, 274-76, 282-283 (1942); *Interstate Circuit, Inc. v. United States*, 306 U.S. 208, 226-227, 230-32 (1939); *United States v. Apple, Inc.*, 791 F.3d 290, 315-20 (2d Cir. 2015), *aff'g* 952 F. Supp. 2d 638, 647-48, 662-65 (S.D.N.Y. 2013); *Toys "R" Us v. FTC*, 221 F.3d 928, 934-36 (7th Cir. 2000); *In re Nexium (Esomeprazole) Antitrust Litig.*, 42 F. Supp. 3d 231, 532-33 (D. Mass. 2014).

Further, Plaintiffs have plausibly alleged that all of the above conduct constitutes an overarching scheme to violate the antitrust laws. All of the alleged acts are interrelated and geared toward suppressing generic competition. Defendants argue that because each discrete aspect of their scheme is purportedly lawful (a claim Plaintiffs vigorously dispute) their conduct in combination cannot constitute an antitrust violation. To the contrary, well established Supreme Court and Circuit case law holds that antitrust cases are not to be judged by "dismembering" them, but by examining them in their totality. *See Namenda II*, 787 F.3d at 654 (citing *Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699 (1962)).

Defendants also argue (1) that the complaint fails to satisfy the statute of limitations despite controlling law that a cause of action for damages accrues each time a direct purchaser pays an overcharge (*Berkey Photo, Inc., v. Eastman Kodak Co.*, 603 F.2d 263, 295-96 (2d Cir. 1979); *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 237-39 (D. Conn. 2015)); and (2) that causation has not been satisfactorily alleged, ignoring the wealth of case law to the contrary.

Finally, Defendants dispute Plaintiffs' allegations by asking the Court to take judicial notice of unpled, contested facts outside the pleadings. *See* Defs.' Br. at 13 n.14. This is "a

plainly improper use of the [judicial notice] doctrine." *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 754 (E.D. Pa. 2014).[5]

As shown below, the motion should be denied.

II. LEGAL STANDARD

A complaint's factual allegations need not be "detailed," but must only "be enough to raise a right to relief above the speculative level on the assumption that all of the complaint's allegations are true." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). A court's task in ruling on a motion to dismiss is to "assess the legal feasibility of the complaint, not to assay the weight of the evidence which might be offered in support thereof." *Hogan v. Fischer*, 738 F.3d 509, 514 (2d Cir. 2013) (quoting *DiFolco v. MSNBC Cable L.L.C.*, 622 F.3d 104, 113 (2d Cir. 2010)). The court must accept all well-pleaded factual allegations in the complaint as true, and draw all reasonable inferences in the plaintiff's favor. *Meyer v. JinkoSolar Holdings Co.*, 761 F.3d 245, 249 (2d Cir. 2014).

III. ARGUMENT

A. The Challenged Agreements Are Anticompetitive Because They Delayed Generic Competition Beyond the Expiration of the '703 Patent

Under *Brulotte*, "any attempted reservation or continuation in the patentee or those claiming under him of the patent monopoly, after the patent expires, whatever the legal device employed, runs counter to the policy and purpose of the patent laws." 379 U.S. at 31 (quoting *Scott Paper Co. v. Marcalus Co.*, 326 U.S. 249, 256 (1945)). *Kimble* reiterated that "[a]llowing even a single company to restrict its use of an expired or invalid patent…would deprive the

[5] *See also Glob. Network Commc'ns, Inc. v. City of New York*, 458 F.3d 150, 156 (2d Cir. 2006) (same); *Am. Fed'n of State v. Bristol-Myers Squibb Co.*, 948 F. Supp. 2d 338, 353-54 & n.15 (S.D.N.Y. 2013) (same); *IHS Dialysis v. Davita, Inc.*, 2013 U.S. Dist. LEXIS 47532, at *8-9 n.2 (S.D.N.Y. Mar. 31, 2013) (same).

consuming public of the advantage to be derived from free exploitation of the discovery. And to permit such a result, whether or not authorized by express contract, would impermissibly undermine the patent laws." *Kimble*, 135 S. Ct. at 2407 (alteration in original) (citations and internal quotation marks omitted). Here, Defendants' agreements with their generic competitors were impermissible "reservations" of their patent monopoly, and amount to naked restraints in violation of Section 1 of the Sherman Act. *See Freedom Holdings, Inc. v. Spitzer*, 357 F.3d 205, 225 (2d Cir. 2004) ("Horizontal agreements among competing sellers to fix prices or restrict output are, absent more, per se violations of Section 1 of the Sherman Act.") (citations omitted); *United States v. Visa U.S.A., Inc.*, 344 F.3d 229, 238 (2d Cir. 2003) ("[P]rice fixing and market division, are considered unreasonable *per se*[.]") (citations omitted).

Defendants claim that their purported pediatric exclusivity entitled them to extend their patent term by six months, but it did not. Compl. ¶¶ 123-124; *see AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1343 (Fed. Cir. 2015) ("The pediatric exclusivity period is not an extension of the term of the patent"); *Altana Pharma AG*, 2012 U.S. Dist. LEXIS 79166, at *9 ("The FDA has stated, '[p]ediatric exclusivity…is not a patent term extension…Rather, it extends the period during which approval of an abbreviated new drug application (ANDA)…may not be made effective by the FDA.'") (quoting Guidance for Industry: Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food Drug and Cosmetic Act, U.S.F.D.A. (Sept. 1999), http://www.fda.gov/OHRMS/DOCKETS/98fr/980265gd.pdf). Defendants waste much ink arguing that the FDA could not grant final approval to any generic until after the pediatric exclusivity period ran (Defs.' Br. at 50-52), but they cannot explain how the FDA nevertheless granted final approval to seven such ANDAs and never revoked those approvals, including during the pediatric exclusivity. Compl. ¶ 133.

Moreover, Defendants' pediatric exclusivity would never prevent final FDA approval for the first filers with which it settled. That is because these first filers filed ANDAs with Paragraph IV certifications, and when a generic files a Paragraph IV certification, the FDA will forebear in granting final approval for six months after patent expiry only when a court hearing the infringement litigation "determines that the patent is valid and would be infringed." Compl. ¶ 125.[6] But Defendants own conduct ensured that a court would never make such a determination, because they settled with their competitors during the infringement actions, up to five years before patent expiry, to bottleneck the market (Compl. ¶ 140), and out of concern that the court could deliver an adverse patent ruling and terminate Defendants' monopoly. Compl. ¶ 109. In so settling, Defendants reserved for themselves something they would never have otherwise had without a victory in the patent case – a lack of competition post patent expiry. This reservation was a *per se* unlawful market division. *See, e.g., Actavis,* 133 S. Ct. at 2242 ("If [a patent holder's] actions go beyond the monopoly powers conferred by the patent, we have held that such actions are subject to antitrust scrutiny.") (citing *United States v. Singer Mfg. Co.*, 374 U.S. 174 (1963)); *United States v. Topco Assocs.*, 405 U.S. 596, 608 (1972) (horizontal restraints are *per se* unlawful).

Further, Defendants' purported pediatric exclusivity commenced in July 2014, and at least four of these generics *already had final approval* years earlier (Compl. ¶ 133) and were free to launch at any time, irrespective of any supposedly available pediatric exclusivity, but-for their agreements with Defendants. *See Ranbaxy Labs., Ltd. v. Burwell,* 82 F. Supp. 3d 159, 169

[6] 21 USC § 355a(c)(1)(B)(II) ("[I]f the drug is the subject of a listed patent for which [a Paragraph IV certification has been submitted], and in the patent infringement litigation resulting from the certification *the court determines that the patent is valid and would be infringed, the period during which an application may not be approved*…shall be extended by a period of six months after the date the patent expires (including any patent extensions).") (emphasis added).

(D.D.C. 2015) ("Once an ANDA has been granted final approval, the manufacturer may begin selling the drug in interstate commerce. *See* 21 U.S.C. § 355(a).").

Defendants' cases are not on-point. Defendants attempt to distinguish *Brulotte* and *Kimble* by citing *AstraZeneca AB*, 782 F.3d 1324, stating that "the Federal Circuit found that *Brulotte* does not control the outcome of a case concerning pediatric exclusivity beyond the term of a patent." Defs.' Br. at 53 (citing 782 F.3d at 1342). Defendants' reading of *AstraZeneca AB* is wrong. Specifically, the *AstraZeneca AB* court found that "[t]he Court's analysis in *Brulotte*…does not apply to a situation as this one[,]" where the brand *defeated the generic* in the infringement action. *AstraZeneca*, 782 F.3d at 1342. Thus under the statute, there had been a "court determin[ation] that the patent is valid and would be infringed" that applied a pediatric exclusivity period specifically against Apotex *and not against other ANDA filers for whom there had been no such determination*. The opinion makes this clear, finding that "although the asserted patents expired on April 20, 2007…the effective date of *Apotex's ANDA approval* [is] set six months later," and that "pursuant to the district court's order, the FDA revoked its earlier approval of *Apotex's ANDA* until [after the pediatric exclusivity expired]." *Id.* at 1341 (emphasis added). By contrast, KUDCO, another ANDA filer that *won* its patent suit, properly launched years before pediatric exclusivity would otherwise have applied had it lost. *Id.* at 1330. And generics Mylan and Lek received final FDA approval and launched at risk without regard to any purported pediatric exclusivity (they only later won their patent disputes against the brand). *Id.* at 1329-30. All the generics in *AstraZeneca AB* were treated as envisioned by the plain text of 21 USC § 355a(c)(1)(B)(II).

Defendants also rely on *AstraZeneca AB v. Impax Laboratories (In re Omeprazole Patent Litigation)*, 490 F. Supp. 2d 368 (S.D.N.Y. 2007), *aff'd*, 536 F.3d 1361 (Fed. Cir. 2008), which

is also highly distinguishable. In that case, the patent expired before the Paragraph IV litigation and the 30-month stay ended. But the brand, AstraZeneca, persisted in seeking to vindicate its patents and the matter was *sub judice*. The generic, Impax, argued that it could remain on the market upon patent expiry despite AstraZeneca's potential pediatric exclusivity, because there was not, and could not be, any court determination of patent validity or non-infringement prior to patent expiry. *Id.* at 378. The court disagreed under the circumstances, and determined that if it later held that the patents at issue were valid and infringed during the existence of the pediatric exclusivity, it may issue an order mandating that the effective date of approval for the generic be no earlier than the expiration of the pediatric exclusivity. *Id.* at 379. It further held that "[n]othing in the language of 21 U.S.C. § 355a(c)(2)(B) requires the Court to render its decision prior to the expiration of the patents." *Id.* at 377. The court did not want to punish the brand because the court could not reach a final decision on the merits in time. *Id.* at 378.

Here, by contrast, the court did not render an opinion on invalidity because the Defendants' own conduct disabled that from ever happening. Specifically, the reverse payment agreements dismissed the lawsuits such that they were *not* being duly litigated or *sub judice*. Moreover, at the time of the settlements, Forest had not even applied for pediatric exclusivity; the generics shortly thereafter had final approval, and the 30-month stays shortly thereafter expired. *Compare* Compl. ¶ 100 (Forest's January 2014 submission for pediatric exclusivity) *with* Compl. ¶¶ 113, 117-118 (settlements were in 2009-2010), Compl. ¶¶ 132-133 (generic approvals in 2010-2011),[7] *and* Compl. ¶ 107 (30-month stays expired in 2010).[8]

[7] Because these approvals were final approvals, the generics could not be required by FDA to convert their Paragraph IV certifications to Paragraph II or III certifications. *In re Omeprazole Patent Litig.*, 490 F. Supp. 2d at 380 ("Once an application is finally approved, the applicant is no longer under an obligation to amend its patent certification.") (citation omitted).

Defendants seek to have their cake and eat it too. They could have chosen to avoid the requirements of 21 U.S.C. § 355a(c)(1)(B)(II) by requiring the generic ANDA filers to convert their Paragraph IV certifications to Paragraph III certifications, which would have subjected the generics to the pediatric exclusivity provisions of 21 U.S.C. § 355a(c)(1)(B)(i)(II). But they did not do so for their own selfish reasons: to create a 180-day exclusivity bottleneck to generic competition. Compl. ¶¶ 138-140. *See generally Joblove v. Barr Labs. (In re Tamoxifen Citrate Antitrust Litig.)*, 466 F.3d 187, 193, 215 (2d Cir. 2006) (patent settlement agreement where first filer generic retains 180-day exclusivity operates to bottleneck other generic competition, but by terms of that settlement, generic (Barr) converted Paragraph IV certification to Paragraph III certification thereby preventing bottleneck). Defendants' citation to *Barr Labs., Inc. v. Thompson*, 238 F. Supp. 2d 236, 242-43, 253 (D.D.C. 2002) is therefore inapposite, as Defendants' own parenthetical shows. Defs.' Br. at 57 (noting that, as part of its settlement with AstraZeneca, Barr had converted from a Paragraph IV to a Paragraph III certification). *Barr Labs*. is also inapposite because Barr's approval was deemed to have been a mere tentative approval under then-prevailing statutes and regulations, not a final approval as existed here for several of the ANDA filers.

B. The Complaint Sufficiently Alleges that Forest Orchestrated a Horizontal Conspiracy Between and Among the First-Filing Generics to Delay Competition in Violation of Section 1 of the Sherman Act

Plaintiffs allege that Forest brokered a horizontal agreement not to compete between and among itself and its would-be generic competitors. Compl. ¶¶ 113-142, 246, 260, 268. The Complaint alleges that several of the generic competitors were preparing to come to market in

[8] Defendants say that the 30-month stays did not end until 2011. Defs.' Br. at 40, n.25. For present purposes, the difference is immaterial.

2011 as soon as their 30-month stays expired. *Id.* ¶¶ 112, 130, 132-133. To avoid the intense competition that would ensue once generic competitors entered the market, Forest began negotiating settlements to delay generic entry. *Id.* ¶¶ 7, 9, 113-115, 136. However, Forest faced a problem: to maintain its monopoly, it had to persuade *all* of the generics to agree not to compete. *Id.* ¶¶ 8-9, 111-142. If even one generic entered the market, Forest would quickly lose market share, and its plan to switch the market to Namenda XR would be undermined. *Id.* ¶¶ 9, 14, 111, 134-141. And each generic co-conspirator faced a related problem: unless it was assured that *all* competitors would promise to stay off the market, no generic would agree to delay its own entry. To agree otherwise would allow its competitors to enter the market when it could not. *Id.* ¶¶ 9-11, 60, 112, 121, 134, 136-137.

To solve the problem, Forest brokered settlement agreements with each of the generics, which collectively assured that no single generic could enter the market earlier than any other, and which provided Forest up to five or six years of unlawful monopoly, which was sufficient time to implement its unlawful switch to Namenda XR. *Id.* ¶¶ 10-11, 54, 121, 134-136, 142. Viewed together, the settlement agreements give rise to a strong inference of collusion far beyond the mere allegation of parallel conduct deemed insufficient in *Twombly*, 550 U.S. at 564, to support an allegation that Forest operated as the "hub" of a "hub and spoke" conspiracy between itself and the settling generics.[9] On a motion to dismiss, Plaintiffs need only allege facts that, taken as true, support a plausible inference that such a conspiracy "was more likely than not." *Apple, Inc.*, 791 F.3d at 318. Allegations of "parallel behavior that would probably not result from chance" meet that test. *See Twombly*, 550 U.S. at 556 n.4 (quoting 6 P. Areeda & H.

[9] In a "hub and spoke" conspiracy, "an entity at one level of the market structure, the 'hub,' coordinates an agreement among competitors at a different level, the 'spokes.'" *Apple, Inc.*, 791 F.3d at 314.

Hovenkamp, *Antitrust Law* ¶ 1425, at 167-85 (2d ed. 2003)). Here, Plaintiffs have alleged copious "plus factors," which "can serve to allow a fact-finder to infer a conspiracy." *Apple, Inc.*, 791 F.3d at 315. Specifically, the Complaint alleges:

1. Forest and the generics had a "common motive to conspire" and implement a market-wide agreement. *Id*. Specifically, by entering into the challenged agreements, Forest kept generic versions of Namenda off the market for as many as five or six years instead of facing competition during that time, and the generics received assurances that no other generic would have a first mover advantage in the market. Compl. ¶¶ 11, 114-115, 120-121, 134-136.

2. Most of the settlement agreements were signed on a "near-simultaneous" basis (*Apple, Inc.*, 791 F.3d at 318). Compl. ¶¶ 113, 117-118.

3. The settling first-filing generics all agreed to an *identical* entry date, and could launch prior to that entry date if (and only if) any other ANDA filer did not join (or cheated on) the conspiracy and entered the market before that date. *Id*. ¶¶ 5, 8, 54, 61, 117, 120.

4. Forest "created a set of economic incentives pursuant to which the Contracts were only attractive to the [generics] to the extent they acted collectively." *Apple, Inc.*, 791 F.3d at 320;[10] *see* Compl. ¶¶ 9-10, 60, 134. That is, the settlement agreements were against each generic's individual self-interests. Specifically, not only did each generic agree to drop its patent litigation, which, if successful, would have entitled them to launch prior to patent expiry (Compl. ¶¶ 5, 114-115, 118), but each generic also agreed to an entry date *after* Forest's patent for Namenda *expired*, meaning the generics chose to forego sales and revenue beyond the date they otherwise could have begun selling generic Namenda. *Id*. ¶¶ 8, 11, 112-122, 131, 268.

5. Each generic agreed that if another generic launched prior to the agreed upon entry date, a settling generic could launch at the same time, rather than cede the market to the interloper – and that this contingency was a necessary condition for each agreement. *Id*. ¶¶ 7, 10-11, 60, 114-115, 120-121. Indeed, "the very act of signing a Contract" which each signatory individually knew was necessary to effect a desired outcome, "signaled a

[10] *See also Toys "R" Us*, 221 F.3d at 935-36 (holding that exclusive-dealing agreements between a retailer and manufacturers that were contrary to the manufacturers' individual self-interest but consistent with their collective interest supported the inference of a horizontal conspiracy in which the retailer participated.); Jonathan B. Baker, *Vertical Restraints with Horizontal Consequences: Competitive Effects of "Most-Favored-Customer" Clauses*, 64 Antitrust L.J. 517, 520-21 (1996) (MFN clauses can "facilitate anticompetitive horizontal coordination" by "reduc[ing] [a company's] incentive to deviate from a coordinated horizontal arrangement.").

clear commitment to…facilitate collective action." *Apple, Inc.*, 791 F.3d. at 317.[11] And "[w]ith contingent launch provisions, each generic Defendant's… commitment only holds firm if in concert with its competitors." *In re Nexium*, 42 F. Supp. 3d at 254.[12]

6. Each settlement agreement contained substantially similar provisions [redacted] *See, e.g.*, Defs.' Ex. 1, § 6.1; Defs.' Ex. 2, § 6.1. Moreover, at least three agreements [redacted] *See, e.g.*, Defs.' Ex. 8, § 4.3(b); Defs.' Ex. 10, § 4.3; Defs.' Ex. 11, § 4.3(b); Compl. ¶¶ 11, 54, 117, 120-121; [redacted]

By 2010 Forest had successfully induced all of the generics that shared a first-to-file date to refrain from entering the market until July 11, 2015. Compl. ¶¶ 7, 113-118. These allegations sufficiently vest the Complaint "with a plausible suggestion of conspiracy" which is all that *Twombly* requires. *Twombly*, 550 U.S. at 566.

The Complaint's allegations mirror those of many other complaints that have, at a minimum, withstood a motion to dismiss. In *Masonite*, the United States alleged that a series of patent settlement agreements between hardboard manufacturers that allowed Masonite to set prices for hardboard constituted an unlawful combination in violation of Section 1. 316 U.S at

[11] *See also In re Nexium*, 42 F. Supp. 3d at 252 ("[C]ourts do treat separate bilateral agreements as evidence of a single conspiracy when the agreements are sufficiently interdependent and made in the context of other plus factors suggesting coordination."); *id.* at 254 (When "concessions are contingent on the actions of others, they are not so clearly discrete," and are not "as consistent with conspiracy as they are with independent action").

[12] *See also Apple, Inc.*, 791 F.3d. at 315 ("the spokes…'adhere to the [hub's] terms,' often because the spokes 'would not have gone along with [the…agreements] except on the understanding that the other [spokes] were agreeing to the same thing.'") (quoting P. Areeda & H. Hovenkamp, *Antitrust Law* ¶ 1402c (3d ed. 2010)).

267-74. The Supreme Court held that the United States sufficiently alleged a conspiracy to fix prices even absent explicit agreement between the manufacturers:

> It is not clear at what precise point of time each appellee became aware of the fact that its contract was not an isolated transaction but part of a larger arrangement. But it is clear that, as the arrangement continued, each became familiar with its purpose and scope…The circumstances surrounding the making of the 1936 agreements and the joinder in 1937 of the two other companies leave no room for doubt that all had an awareness of the general scope and purpose of the undertaking. As this Court stated in the *Interstate Circuit* case (p.227): "It is elementary that an unlawful conspiracy may be and often is formed without simultaneous action or agreement on the part of the conspirators…***Acceptance by competitors, without previous agreement, of an invitation to participate in a plan, the necessary consequences of which, if carried out, is restraint of interstate commerce, is sufficient to establish an unlawful conspiracy under the Sherman Act.***"

Id. at 275 (emphasis added). Importantly, in *Masonite*, just as here, the government alleged that the participation of each competitor was essential for the scheme to achieve its purpose and that Masonite shared the details of its settlement agreements with each of its competitors. *Id.* at 270. Moreover, even were Defendants to establish that the first settlement agreement (with Amneal) was negotiated [redacted] "that its contract was not an isolated transaction but part of a larger arrangement," *id.* at 275, demonstrates that Forest contemplated and achieved concerted action among the generics.

Similarly, in *Apple, Inc.*, the district court found that Apple had orchestrated a *per se* unlawful horizontal conspiracy among book publishers to fix and raise the prices of e-books. 952 F. Supp. 2d at 694. Reiterating the rulings in other hub-and-spoke conspiracy cases such as *Toys "R" Us* and *Interstate Circuit*, the court stated that the "'hub' defendant's liability in those cases existed because 'there was no doubt…that the 'hub' defendant was aware of the purported scheme – the only question was whether the horizontal defendants agreed to it." *Id.* at 707 (alteration in original) (citation omitted). The court found the circumstantial evidence sufficient

to support a verdict against Apple, including that "each of the Publisher Defendants shared the identical goal" of raising prices; the arrangement "protected Apple from price competition"; "the rise in trade e-book prices…was large and essentially simultaneous"'; the agreements "deprived each [competitor] of a stream of expected revenue"; and "each of the [competitors] acted in identical ways." *Id.* at 693. In addition, the court noted that the Publisher Defendants each knew of the others' agreements with Apple (*id.* at 666), and that Apple considered it essential that as many publishers as possible enter into similar agreements with Apple in order for the scheme to work. *Id.* at 673. These same characteristics are present in the agreements among Defendants and the generics here.

The Second Circuit affirmed the liability verdict, noting that "[t]he MFNs in Apple's Contracts created a set of economic incentives pursuant to which the Contracts were only attractive to the Publisher Defendants to the extent they acted collectively." *Apple, Inc.*, 791 F.3d at 320. This, among other "plus factors," "provide[d] strong evidence that Apple consciously orchestrated a conspiracy among the Publisher Defendants." *Id.* at 316. That the generics would only agree to stay off the market so long as the other generics did so (e.g., Compl. ¶¶ 114-115, 120-121) makes this case analogous to *Apple, Inc*.

Toys "R" Us further supports the allegations of an overall conspiracy, even without an explicit agreement between the generic "spokes." In that case, the FTC alleged that TRU, a large toy retailer, orchestrated an agreement between numerous manufacturers to boycott low-priced warehouse clubs. 221 F.3d. at 932. As here, each competitor's promise to not sell to these large customers was contrary to its independent self-interest and thus, each competitor was unwilling to limit those sales without the assurance that the other competitors would too. *Id.* An FTC administrative law judge concluded that TRU orchestrated an unlawful boycott by manufacturers

of the warehouse clubs and that the "agreements between TRU and the individual toy manufacturers, 'entered into *seriatim* with clear anticompetitive effect, violate Section 1 of the Sherman Act.'" *Id.* at 933 (citation omitted).

On appeal to the Seventh Circuit, TRU contended that there was insufficient evidence of a horizontal conspiracy with TRU as the orchestrator. *Id.* at 934. The Seventh Circuit disagreed, finding that "[t]hese manufacturers were in effect being asked by TRU to reduce their output…, and as is classically true in such cartels, they were willing to do so only if TRU could protect them against cheaters." *Id.* at 936. So too here, Forest asked the generics to reduce their output (to forgo all sales) and they were willing to do so only if Forest could protect them from "cheaters." The contingent launch clauses in the agreements provided a settling generic with protection it needed against the risk that while it stayed off the market, its fellow generics would launch. Compl. ¶¶ 5, 8-10, 52, 54, 114-115, 120-121. That "risk," of course, is called *competition*, and companies are not entitled to protection from it.

In *In re Nexium*, a reverse payment case where plaintiffs, as here, alleged an overall conspiracy based in significant part on the existence of contingent launch clauses in each agreement, the court denied a motion for summary judgment on conspiracy. The court found that there were sufficient grounds to proceed to a jury trial based on evidence that "[e]ach agreement defined th[e] entry date in nearly identical contingent terms" (42 F. Supp. 3d at 249); "[t]he effect of th[e] contingent launch provision was to commit each signing Generic Defendant to refrain from launching generic Nexium until [the same day] unless another generic manufacturer found a way to legally enter the market on an earlier date" (*id.*); and even though "there is no evidence that any of the Generic Defendants communicated with each other," "the terms of the[] agreements were all publicized[.]" *Id.*

The court determined that "the intrinsic interdependence of the contingent launch clauses [was] sufficient evidence of connection between the Generic Defendants[.]" *Id.* at 256. Thus, the court held that it is not necessary for plaintiffs to prove "a single agreement…expressly made" by all participants with one another. *Id.* at 253. Rather, "contingent launch clauses themselves [are] the mechanism of a single agreement." *Id.* at 254 ("[N]o evidence of [a single overarching agreement] is necessary to form a Sherman Act conspiracy."); *see also King Drug Co. of Florence v. Cephalon, Inc.*, 702 F. Supp. 2d 514, 532-34 (E.D. Pa. 2010) (allegations of contingent launch clauses, identical generic entry dates, and common motive amongst generics were sufficient to survive a motion to dismiss.).[13]

Defendants point to *In re Actos End Payor Antitrust Litigation*, 2015 U.S. Dist. LEXIS 127748 (S.D.N.Y. Sept. 22, 2015), which is distinguishable as it lacks many of the plus factors identified here; in particular, that the brand [redacted] with each generic and that the brand extended its patent by agreement with each first filer in violation of *Brulotte*. Moreover, *Actos* does not appear to comport with the Second Circuit's controlling holding in *Apple, Inc.* Defendants' motion to dismiss Plaintiffs' single-conspiracy claims should be denied. *See United States v. Payne*, 591 F.3d 46, 62 (2d Cir. 2010) (existence of single conspiracy or multiple conspiracies is fact question for the jury).

[13] Plaintiffs' *Masonite* claim was subsequently dismissed on summary judgment. *King Drug Co. of Florence v. Cephalon, Inc.*, 2014 U.S. Dist. LEXIS 84818, at *57-63 (E.D. Pa. June 23, 2014). Plaintiffs believe the dismissal was in error. More importantly for present purposes, the dismissal came after the claim survived a motion to dismiss and development of a full record.

C. The Complaint Sufficiently Alleges a Rule of Reason Claim Against Forest and Merz, or, Alternatively, Plaintiffs Should Be Granted Leave to Amend their Complaint to Include Factual Detail from the Settlement Agreements

1. The Supreme Court's *Actavis* Decision

In *Actavis*, the Supreme Court held that "large" and "unexplained" "reverse payments" could have substantial anticompetitive effects and therefore must be evaluated under the rule of reason. *Actavis*, 133 S. Ct. at 2236-37. *Actavis* establishes principles that are important in evaluating the instant challenge to reverse payment agreements.

First, collusion among competitors is "the supreme evil of antitrust." *Id.* at 2233 (quoting *Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 408 (2004)). A patent holder may not "pay a competitor to respect its patent and quit its patent invalidity or noninfringement claim without any antitrust scrutiny[.]" *Id.* Such an agreement can "unreasonably diminish competition in violation of the antitrust laws." *Id.* at 2227.

Second, *Actavis* held that a large reverse payment has the "potential for genuine adverse effects on competition," because it "amounts to a purchase by the patentee of the exclusive right to sell its product." *Id.* at 2234 (citing *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 460-61 (1986)). Thus, "if the basic reason" for the brand manufacturer's payment to its generic competitor "is a desire to maintain and to share patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement." *Actavis*, 133 S. Ct. at 2236-37; *see also id.* at 2234-35 ("[P]ayment in return for staying out of the market – simply keeps prices at patentee-set levels…while dividing that [monopoly] return between the challenged patentee and the patent challenger. The patentee and challenger gain; the consumer loses."); *United Food & Commer. Workers Local 1776 v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1065 (N.D. Cal. 2014) ("If a generic manufacturer abandons a viable claim in exchange for a portion of the brand-name manufacturer's monopoly profits, then the brand-

name manufacturer is able to retain the monopoly profits that would otherwise be lost in the competitive market.") (internal quotation marks omitted).

Third, *Actavis* recognized that a reverse payment carries the potential for anticompetitive effects whether or not the patent is valid or infringed; a payment to avoid the *risk of competition* is itself harm to competition, and therefore is subject to scrutiny under the rule of reason. *See King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, 401-03 (3d Cir. 2015) ("*Lamictal*") (rule of reason liability may be found "notwithstanding the possible validity or infringement of the patent in question"). As the Third Circuit recently opined:

> In the *Actavis* Court's view, reverse payments are problematic because of their potential to negatively impact consumer welfare by preventing the *risk of competition*, which arises from *expected* litigation outcomes…. "even a small risk of invalidity" may not justify a "large payment" (presumably enabled by "patent-generated monopoly profits") that "likely seeks to prevent the *risk of competition*." And, the Court reiterated, it is the prevention of that risk of competition – eliminating "the risk of patent invalidation or a finding of noninfringement" by "paying the challenger to stay out" of the market (for longer than the patent's strength would otherwise allow) – that "constitutes the relevant anticompetitive harm" which then must be analyzed under the rule of reason.

Id. at 403-04 (emphasis added) (citations omitted) (quoting *Actavis*, 133 S. Ct. at 2236-37).

Fourth, *Actavis* expressly held that the merits of the underlying patent case need not be litigated to conduct a rule of reason analysis of a reverse payment where the payment is large and unexplained. Specifically, the Court recognized that "[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival." *Actavis*, 133 S. Ct. at 2236. This, in turn, "suggests that the payment's objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market – the very anticompetitive consequence that underlies the claim of antitrust unlawfulness." *Id.*; *see also Lamictal*, 791 F.3d at 402 ("The inference may be drawn from a reverse payment that the patent holder is paying the alleged infringer to defend 'a

right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed by the generic product.'") (quoting *Actavis*, 133 S. Ct. at 2234); *In re Aggrenox*, 94 F. Supp. 3d at 240 (same). Thus, under *Actavis*, the rule of reason does not require a plaintiff to "litigate the patent's validity, empirically demonstrate the virtues or vices of the patent system, present every possible supporting fact or refute every possible pro-defense theory." *Actavis*, 133 S. Ct. at 2237.

Finally, *Actavis* teaches that drug companies can settle patent disputes without making large reverse payments – "for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, *without the patentee paying the challenger to stay out* prior to that point." *Id.* (emphasis added).

2. The Rule of Reason

Actavis applies traditional fact-intensive rule of reason analysis to determine whether reverse payment agreements are anticompetitive. *Actavis*, 133 S. Ct. at 2231, 2237-38; *see also Lamictal*, 791 F.3d at 410-13 (applying rule of reason burden shifting); *In re Nexium*, 42 F. Supp. 3d at 262 (per *Actavis*, reverse payments are analyzed under the rule of reason). In rule of reason cases, "Plaintiffs bear the initial burden to demonstrate an actual adverse effect on competition," such as higher prices, lower output, reduced product quality or reduced consumer choice as a result of the challenged agreement. *Geneva Pharms. Tech. Corp. v. Barr Labs., Inc.*, 386 F.3d 485, 509 (2d Cir. 2004); *see also Visa U.S.A., Inc.*, 344 F.3d at 238 (same). "[T]he burden then shifts to defendant to offer evidence that its conduct had pro-competitive effects." *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98, 104 (2d Cir. 2010). A procompetitive justification is a defense, for which a defendant (not a plaintiff) bears the burdens of production and persuasion. *NCAA v. Bd. of Regents of Univ. of Okla.*, 468 U.S. 85, 113 (1984) (a defendant carries "a heavy burden of establishing an affirmative defense which

competitively justifies…deviation from the operations of a free market"); *Visa U.S.A., Inc.*, 344 F.3d at 238 ("[T]he burden of production shifts to the defendants, who must provide a procompetitive justification for the challenged restraint."); *Virgin Atl. Airways v. British Airways Plc*, 257 F.3d 256, 264 (2d Cir. 2001) ("[T]he burden shifts to [defendant] to establish the procompetitive value of its…agreements."). In every *Actavis* case thus far litigated, courts have held that it is *defendant's burden* to proffer and prove justifications.[14]

"If defendant is able to offer such proof, the burden shifts back to plaintiff, who must prove that any legitimate competitive effects could have been achieved through less restrictive alternatives." *Geneva Pharms. Tech. Corp.*, 386 F.3d at 507.[15] The final step in the rule of reason analysis is performed by the jury. *Id.* ("Ultimately, the factfinder must engage in a careful weighing of the competitive effects of the agreement -- both pro and con -- to determine if the effects of the challenged restraint tend to promote or destroy competition.")

Under *Actavis*, at the pleading stage plaintiffs need only plausibly allege reverse payments sufficiently large to get patent defendants to quit the patent fight. Plaintiffs have alleged such large reverse payments (Compl. ¶¶ 114, 119, 246(a)), that resulted in delayed

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[14] *See, e.g.*, *Lamictal*, 791 F.3d at 412 (burden is on defendant to justify reverse payments); *In re Solodyn Antitrust Litig.*, 2015 U.S. Dist. LEXIS 125999, at *33-34 (D. Mass. Aug. 14, 2015) ("fair value for services" is defendant's burden and cannot be resolved on the pleadings); *In re Aggrenox*, 94 F. Supp. 3d at 244-45 (burden is on defendant to show procompetitive effects, and "fair value" depends on evidence in defendants' exclusive possession); *King Drug Co. of Florence v. Cephalon, Inc.*, 88 F. Supp. 3d 402, 405, 412, 419 (E.D. Pa. 2015) (same); *Teikoku*, 74 F. Supp. 3d at 1064-65, 1072 (because burden is on defendant to justify reverse payments, "fair value" cannot be adjudicated on a motion to dismiss); *In re Nexium*, 42 F. Supp. 3d at 262, 264 (same); *In re Cipro Cases I & II*, 348 P.3d 845, 867 (Cal. 2015) (same); *Niaspan*, 42 F. Supp. 3d at 753 ("Twombly does not require an antitrust plaintiff to plead facts that, if true, definitively rule out all possible innocent explanations.").

[15] Thus Defendants' argument that Plaintiffs impermissibly "second guess" Defendants' patent settlement agreements (Defs.' Br. at 44) is inaccurate: Whether a less restrictive agreement could have been struck absent the reverse payments is a standard part of "rule of reason" analysis.

generic Namenda competition and caused higher memantine prices and lower memantine output. *Id*. ¶¶ 5, 8, 11, 15, 131, 135-137, 141, 229, 232, 241, 255, 265, 274. As the litigation proceeds, it is the defendants' burden to make the factually intensive showing and convince the jury "that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term." *Actavis*, 133 S. Ct. at 2235-36. Necessarily then, a defendant's alleged procompetitive justifications cannot support dismissal on the pleadings. *See Reading Int'l, Inc. v. Oaktree Capital Mgmt. LLC*, 317 F. Supp. 2d 301, 321-22 (S.D.N.Y. 2003) (declining to analyze procompetitive justification at pleadings stage); *Six W. Retail Acquisition, Inc. v. Sony Theater Mgmt. Corp.*, 2000 U.S. Dist. LEXIS 2604, at *92-94 (S.D.N.Y. Mar. 8, 2000) (on a motion to dismiss, a plaintiff need only allege anticompetitive conduct to survive).

3. Plaintiffs Have Alleged a Large Reverse Payment Under *Actavis*

A patent holder may not "pay a competitor to respect its patent and quit its patent invalidity or noninfringement claim without any antitrust scrutiny[.]" *Actavis*, 133 S. Ct. at 2233. Rather, "if the basic reason" for the brand's payment to its generic competitors "is a desire to maintain and to share patent-generated monopoly profits, then, in absence of some other justification, the antitrust laws are likely to forbid the arrangement." *Id.* at 2227.[16]

[16] Under *Actavis*, the determination of whether a payment is "large" is a qualitative one is measured by "its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification." *Id.*; *see also King Drug Co. of Florence*, 88 F. Supp. 3d at 417 ("Plaintiffs respond that a reverse payment is sufficiently large if it exceeds saved litigation costs and a reasonable jury could find that the payment was significant enough to induce a generic challenger to abandon its patent claim….*Actavis* supports Plaintiffs' approach.").

That is exactly what Plaintiffs allege here: In the ten (10) settlement agreements with the first-filing generics,[17] each first-filing generic "receive[d] something of immediate and substantial value (such as cash and/or protection from competition with each other)" from Forest well in excess of any reasonable approximation of Forest's saved litigation expenses or any fair value for services, in consideration for which all of those generics quit their patent challenges and agreed to delay launching their generic products. Compl. ¶¶ 5, 7, 112, 114-120, 246.

Although Plaintiffs were unable to allege specific payment amounts because the settlements were not publicly disclosed, the Complaint alleges that the aggregate payments to [redacted]

[17] Eleven generics were first to file their ANDAs. *See* Compl. ¶ 106. One of those generics, Barr, was acquired by another, Teva, prior to settlement with Forest. *Id.* ¶ 103.

[18] Defendants criticize Plaintiffs' allegations concerning the nature and amount of the payments to the generic first-filers as "threadbare." Defs.' Br. at 36. Of course, Plaintiffs did not have access to the settlement and related agreements until after the Complaint was filed. As such, some of the agreement details discussed herein are not extensively alleged in the Complaint. Should the Court find the Plaintiffs' complaint allegations to be insufficient in this regard, Plaintiffs respectfully request the opportunity to amend their complaint to include detailed payment information that was unavailable to the Plaintiffs when filing the Complaint. However, one court in this Circuit has recently held that such precision is not necessary. *See In re Aggrenox*, 94 F. Supp. 3d at 244 ("It is also clear that very precise and particularized estimates of fair value and anticipated litigation costs may require evidence in the exclusive possession of the defendants, as well as expert analysis, and that these issues are sufficiently factual to require discovery. I cannot conclude simply from the absence of precise figures that the pleadings represent formulaic recitations of elements and allegations that fail to rise above the speculative[.]").

[redacted]

The last two first-filing generics to settle, [redacted]

[redacted]

[redacted]

4. There Is No Safe Harbor Reverse Payment Amount under *Actavis*

Defendants challenge the sufficiency of Plaintiffs' *Actavis* claim, suggesting that there is a safe harbor for reverse payments of up to $7 million for attorneys' fees and costs, and arguing that the individual cash payments to the first-filers cannot raise an inference of an anticompetitive reverse payment. Defs.' Br. at 36-37.

Actavis provides no such safe harbor, and even if it did, the cash payments here exceed any conceivable safe harbor amount. With respect to the relationship between the size of the reverse payment and saved litigation costs, *Actavis* provides:

> [T]he likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.

133 S. Ct. at 2237. Not only does this language not provide any specific dollar amount below which a reverse payment can escape all antitrust scrutiny, it expressly provides that the size of the payment in relation to the payor's (i.e., Forest's) anticipated future litigation costs is one measure by which the anticompetitive nature of a payment can be determined.

Actavis expressly refers to the "*payor's* anticipated future litigation costs" in its discussion of possible procompetitive justifications that a defendant would need to prove. *Id.* (emphasis added). Compensation for the *payee's* (i.e., the generic's) spent litigation costs is in no way shielded from antitrust scrutiny. Here, all of the license agreements expressly state that the payments are intended to compensate the *generics* for *their* spent litigation costs. As such, they are all facially outside of the scope of any litigation cost defense discussed in *Actavis*.

The Defendants cannot contest that the aggregate cash payments to the first-filing generics under the settlement and license agreements exceed $[redacted]

5. The Antitrust Concerns that Underlie *Actavis* Preclude Dismissal

Large payments violate of *Actavis* when they are payment to avoid risk of patent invalidation or a finding of non-infringement.[19] The *Actavis* analysis is much more straightforward where there is only one generic first-filer and few generics in total (as in *Actavis*).

Here, with as many as eleven potential first-filers, all competing to be first to market within the 180-day exclusivity period, Forest needed to pay off many more competitors in order to avoid the risk of an adverse patent determination. But because each generic recognized that if they launched on their shared exclusivity date, they would quickly commoditize the market, they

[19] *See In re Aggrenox*, 94 F. Supp. 3d at 243 ("Large reverse payments that are not particularly large in relation to the value of the patent may show confidence in the patent, but if they represent payment *to avoid the risk of invalidation*, then they still run afoul of *Actavis*.") (emphasis in original).

could be bought-off for less than they would otherwise demand if any of them were the only generic with exclusivity. *See* Compl. ¶ 106 (noting shared exclusivity). Nothing in *Actavis* suggests or implies that a brand monopolist's conduct becomes progressively less violative as the number of potential competitors it pays off increases. To the contrary, *Actavis* teaches that the facts and circumstances must be considered to determine whether the payments at issue were large in the sense that they were sufficient to induce the generics to quit their patent challenges. Thus, the arbitrary imposition of a safe harbor figure focused on the dollar amounts received by each generic would, in fact, facilitate the very anticompetitive harms that *Actavis* sought to prevent in situations where there are multiple first-filing generics.

Plaintiffs allege that with the unprecedented number of potential first-filers, "the first to settle would be worried that, whatever entry date it had agreed to, one or more of its fellow Potential First Filing Generics would get a 'better' deal, i.e., an earlier entry date, in its own subsequent settlement with Forest and Merz" and "the last settling Potential First-Filing Generic would have every incentive to hold out for the earliest date of all." Compl. ¶¶ 9-10. This resulted in anticompetitive contingent launch clauses that harmed competition. *See, e.g.*, *Apple, Inc.*, 952 F. Supp. 2d at 694 (most-favored-nation clauses "did not promote competition, but destroyed it"); Michael Carrier, *Payment After Actavis*, 100 Iowa L. Rev. 7, 40 (2014) ("In reducing the later-filing generic's incentive to prosecute litigation, a [contingent launch] clause provides a settling generic with something it could not have obtained through litigation.").

D. The Complaint Sufficiently Alleges that the Namenda IR-to-Namenda XR Product "Hop" Was Exclusionary

1. The District Court and Second Circuit Opinions Show That Defendants' Product Hop Scheme is Not Only A Plausible Violation of § 2 of the Sherman Act, But Can Be Proven With A Substantial Likelihood of Success

It is frankly astonishing that Defendants argue that Plaintiffs have failed to allege a plausible Sherman Act § 2 violation in the nature of an illegal "hard switch" product hop. A court of coordinate jurisdiction in this very district, and the Second Circuit Court of Appeals, have both ruled, in findings of fact and conclusions of law that have been affirmed, that Defendants did, in fact, engage in illegal "hard switch" conduct that violated Section 2 of the Sherman Act under the governing "rule of reason." *See New York v. Actavis, PLC*, 2014 U.S. Dist. LEXIS 172918 (S.D.N.Y. Dec. 11, 2014) ("*Namenda I*"), *aff'd*, 787 F.3d 638 (2d Cir. 2015). The findings of fact and conclusions of law at issue in *Namenda I* and *Namenda II*, an action for both injunctive relief and damages,[20] comprise the very same facts and evidence that form the averments of Plaintiffs' complaint here.

Following a full evidentiary hearing on those facts and that evidence, Defendants were found to possess monopoly power, *Namenda I*, 2014 U.S. Dist. LEXIS 172918, at *37-45 (Findings of Fact 56-70); *id.* at *97-98, *101-02, *104 (conclusions of law); to have wrongfully exercised that monopoly power by engaging in exclusionary conduct in the nature of "hard switch" product hopping, *id.* at *45-72 (Findings of Fact 71-125); that their conduct had actual anticompetitive effects that harmed consumers and competition, *id.* at *72-91 (Findings of Fact 126-167); *id.* at *107-09 (conclusions of law); that all of Defendants' purported procompetitive justifications for their "hard switch" conduct were pretextual, *id.* at *67-72 (Findings of Fact 113-

[20] *See Namenda I*, 2014 U.S. Dist. LEXIS 172918, at *7 (seeking injunctive relief, restitution, and "damages to injured parties").

125); *id.* at *109-12 (conclusions of law); and that even if they were to some extent cognizable, Defendants' procompetitive justifications for their "hard switch" conduct were outweighed by the harm to competition that conduct caused, *id.* at *112-13. The Second Circuit affirmed in all respects: monopoly power, harm to competition, and the lack of non-pretextual justifications. *Namenda II*, 787 F.3d. at 651-52 (Defendants had 100% of the relevant market and thus monopoly power); *id.* at 655 (anticompetitive harm); *id.* at 658 (all asserted justifications were pretexts). The precise holding affirmed by the Second Circuit was that the plaintiff (New York) had proven not only that its averments were plausible (the question on this motion), but that it had a substantial likelihood of succeeding in proving a Section 2 violation. *Id*. at 643 ("New York has demonstrated a substantial likelihood of success on the merits of its claim under the Sherman Act, 15 U.S.C. § 2"); *id.* at 650-51 (same). A substantial likelihood of success on the merits of averments necessarily means that those averments — the very ones pled by Plaintiffs here — are at least plausible and thus satisfy Rules 8(c) and 12(b)(6). *See Vaguely Qualified Prods. LLC v. Metro. Transp. Auth.*, 2015 U.S. Dist. LEXIS 138340, at *29, *31 (S.D.N.Y. Oct. 7, 2015) (McMahon, J.) (upon a finding that the plaintiff "established a clear or substantial likelihood of success on the merits" and issuing a preliminary injunction, ruling that, "*Obviously*, the motion [to dismiss for failure to state a claim] is denied insofar as it is directed at Plaintiff's claim for relief….") (emphasis added); *ESPN, Inc. v. Quiksilver, Inc.*, 586 F. Supp. 2d 219, 229 (S.D.N.Y. 2008) (McMahon, J.) (denying a motion to dismiss, and noting that "[t]he test on a motion directed at a pleading is much less stringent [than the standard for a preliminary injunction]").

Given the now-controlling law that a unanimous panel of the Second Circuit handed down concerning "hard switch" product hopping, Defendants do not (because they cannot) argue that Plaintiffs' averments, which are identical to the facts found in *Namenda I* and affirmed in

Namenda II, do not state a cognizable claim under Section 2's "rule of reason" standard. *See* Compl. ¶¶ 54, 78, 86-87, 89, 142-192.[21] Instead, Defendants' response is to deny the judicial findings about what they have actually done, in a misguided effort to impermissibly contradict the averments of Plaintiffs' complaint that are based on and incorporate those findings. *See Glob. Network Commc'ns, Inc.*, 458 F.3d at 156 (improper for court to rely on defendants' proffered statements "to make a finding of fact that *controverted* the plaintiff's own factual assertions set out in its complaint") (emphasis in original); *Vaher v. Orangetown*, 916 F. Supp. 2d 404, 429 (S.D.N.Y. 2013) ("[Defendant's] suggestion directly contradicts the allegations in the Amended Complaint and thus may not be considered on a Rule 12(b)(6) motion.").

2. Defendants Engaged in "Hard Switch" Conduct by Announcing the Imminent Withdrawal of Namenda IR

First, Defendants argue that their "hard switch" conduct never occurred, was merely inchoate, and was in fact prevented from occurring (or at least cured and undone) by Judge Sweet's injunction. Defs.' Br. at 1 ("[T]he hard switch *never happened*.") (emphasis in original); *id.* at 2 (same); *id.* at 12 ("Before Forest altered distribution of Namenda IR in any way…."); *id.* at 15-16 ("Whatever concerns Plaintiffs may have about Forest's plans, the injunction prevented Forest from withdrawing Namenda IR or changing its distribution."); *id.* at 16-17 (claiming no competitive effect); *id.* at 17 ("[D]ue to the injunction, Namenda IR was never withdrawn from the market."); *id.* at 18 (alleging that conduct "clearly lack[ed] an actual hard switch").

[21] Following most other product hopping decisions, the district court in *Namenda I* adopted the structured rule-of-reason formulation for evaluating product hopping conduct that was first articulated in the *Microsoft* decision from the Court of Appeals for the District of Columbia Circuit. *Namenda I*, 2014 U.S. Dist. LEXIS 172918, at *105-07 (citing *United States v. Microsoft*, 253 F.3d 34, 58-59 (D.C. Cir. 2001)). The Court of Appeals in *Namenda II* affirmed this approach. *Namenda II*, 787 F.3d at 652-54.

Preliminarily, Defendants fail to identify the legal grounding for this argument: are they (impermissibly) contradicting Plaintiffs' complaint on a motion to dismiss? Are they (impermissibly) asserting an affirmative defense (like accord and satisfaction or "impossibility") in the form of a motion to dismiss?[22] Are they silently converting their Notice of Motion (ECF No. 55) and instead proceeding under Rule 12(b)(1), arguing mootness? Defendants do not explain or develop any of this in briefing and so the Court is left to wonder. Plaintiffs respectfully request leave to further respond if and when Defendants decide and explain the legal theory under which they are proceeding.

But whatever the basis, Defendants' arguments are demonstrably false, as shown by the decisions *Namenda I* and *Namenda II* on which they purport to rely. According to findings of fact by Judge Sweet, Defendants did, in fact, announce the immediate withdrawal of Namenda IR, and did, in fact, ask Medicare to remove Namenda IR from its formulary reference file. *See Namenda I*, 2014 U.S. Dist. LEXIS 172918, at *48-49 (on February 14, 2014, commencing its "forced switch" strategy, Defendants publicly announced, in press releases, to the FDA, and in open letters to physicians and caregivers, that they would imminently withdraw Namenda IR from the market) (Finding of Fact 77); *id.* at *49 (physicians interpreted the announcement of imminent product withdrawal as a warning to switch their patients) (Finding of Fact 78); *id.* at *50 (Defendants asked Medicare to remove Namenda IR from its formulary reference file) (Finding of

[22] Affirmative defenses are generally improper to raise on a Rule 12(b)(6) motion. *E.g.*, *N.J. Carpenters Health Fund v. Royal Bank of Scot. Grp., PLC*, 709 F.3d 109, 125 n.10 (2d Cir. 2013) ("[w]hether the underwriters conducted a reasonable investigation pertains only to an affirmative defense that the Defendants-Appellees may raise in future proceedings" and not a motion to dismiss); *Castro v. United States*, 34 F.3d 106, 111 (2d Cir. 1994) (error to grant Rule 12 motion based on affirmative defense of qualified immunity); *IHS Acquisition XV v. Kings Harbor Care Ctr.*, 1999 U.S. Dist. LEXIS 5448, at *7 (S.D.N.Y. Apr. 16, 1999) (affirmative defense of illegality could not be considered on motion to dismiss).

Fact 80). The Second Circuit affirmed these findings. *Namenda II*, 787 F.3d at 648 ("On February 14, 2014, Defendants publicly announced that they would discontinue Namenda IR on August 15, 2014, notified the FDA of their plans to discontinue Namenda IR, and published letters on their websites urging caregivers and healthcare providers to 'discuss switching to Namenda XR' with their patients. Defendants also sought to convert Namenda IR's largest customer base, Medicare patients, to XR by sending a letter to the Centers for Medicare & Medicaid Services requesting that the agency remove IR from the formulary list, so that Medicare health plans would not cover it."); *id.* at 648 ("The hard switch began on February 14, 2014 with the announcement of Defendants' intention to withdraw Namenda IR and was suspended in September 2014 when Defendants agreed to a 'standstill' during the litigation proceedings described below. Because a manufacturer does not simply withdraw a drug at once, absent pressing safety concerns, announcing the imminent discontinuation of a drug is tantamount to withdrawal.").

And as found in *Namenda I* and *Namenda II*, these tactics had the very effects that Defendants intended. In anticipation of the announced lack of availability of Namenda IR, approximately 50% of patients were switched from Namenda IR to Namenda XR. *See Namenda I*, 2014 U.S. Dist. LEXIS 172918, at *81-82 ("To date, about 50% of existing patients have converted from Namenda IR to Namenda XR in anticipation of the lack of availability of Namenda IR.") (Finding of Fact 142); Compl. ¶¶ 176, 185. It is that very effect — moving patients to the reformulated product that is not subject to imminent generic competition — that is the primary reason product hopping exerts anticompetitive harm. *See Namenda I*, at *108, *110;

accord Namenda II, 787 F.3d at 642-43, 654, 655-56.[23] Judge Sweet found that only a small number of those patients are expected to ever switch back. *Namenda I*, 2014 U.S. Dist. LEXIS 172918, at *27 ("A brand manufacturer that has successfully achieved a switch to a follow-on product can expect that most 'switched' patients will not make a second switch back to the original product.") (Finding of Fact 36); *id.* at *48 (Finding of Fact 76) (reverse commuting "very difficult" to achieve); *id.* at *69 (Finding of Fact 116) (same); *id.* at *79 (small percentage of reverse commuting can be expected) (Finding of Fact 138); *id.* at *82 (same) (Finding of Fact 143). The Second Circuit credited this finding. *Namenda II*, 791 F.3d at 655 ("[R]everse commute by patients from XR to generic IR [is] highly unlikely."); *id.* at 656 (same).

While it is true that *Namenda I* and *Namenda II* were primarily focused on preventing irreparable harm (suppressed generic substitution) that would be realized once generic Namenda IR entry occurred in July of 2015, this observation does not detract one bit from the findings of the district court, affirmed by the Court of Appeals, that Defendants' "hard switch" conduct had already begun with their announcement of imminent Namenda IR withdrawal, and had already caused Namenda IR patients to be switched to Namenda XR in substantial numbers, with little hope of "reverse commuting." Defendants' attempts to challenge the precise number or percentage of patients or prescriptions switching from IR to XR that were provoked by Defendants' announcement, or to shed doubt upon the degree to which switching back or "reverse commuting" occurred, or to suggest that the injunction had the capacity to undo the substantial switching that had already occurred (Defs.' Br. at 25-27) are obviously questions of evidence that are simply not proper on a motion to dismiss. *See Hinds Cty. v. Wachovia Bank N.A.*, 700 F.

[23] The Second Circuit remarked that there was "no genuine dispute" that this was precisely Defendants' intent. *Namenda II*, 787 F.3d at 653 n.25.

Supp. 2d 378, 390 (S.D.N.Y. 2010) ("The task of the court in ruling on a motion to dismiss is to assess the legal feasibility of the complaint, not to assay the weight of the evidence which might be offered in support thereof.") (citation and internal quotation marks).

3. Defendants' Announcement of the Imminent Withdrawal of Namenda IR Is, As a Matter of Law, "Hard Switch" Conduct, Not "Soft Switch" Conduct

Second, Defendants say that their "hard switch" conduct of announcing the imminent withdrawal of Namenda IR and asking CMS to remove Namenda IR from its formulary was not cognizably illegal because those things are really just "soft switch" conduct, like marketing or product promotion. Defs.' Br. at 18-19 ("Because there was no hard switch, Plaintiffs must rely instead on a 'soft switch' theory. * * * Plaintiffs point to: (1) the February 2014 announcement that Namenda IR would be discontinued in the future; and (2) Forest's request that the Centers for Medicare and Medicaid Services ('CMS') remove Namenda IR from their reference list for 2015 in anticipation of discontinuance."). Defendants' characterization of their announcement of imminent withdrawal and their notification to CMS as "soft switch" conduct is inaccurate. *Namenda I* and *Namenda II* both establish the controlling law in this Circuit: that announcing the imminent withdrawal of the prior formulation of a drug product is "hard switch" conduct, not "soft switch" conduct. *Namenda II*, 791 F.3d at 648 ("The hard switch began on February 14, 2014 with the announcement of Defendants' intention to withdraw Namenda IR[.] * * * [A]nnouncing the imminent discontinuation of a drug is tantamount to withdrawal."); *Namenda I*, 2014 U.S. Dist. LEXIS 172918, at *48-49 ("On February 14, 2014, Forest began the 'forced switch' by publicly announcing that Namenda IR tablets would be discontinued on August 15, 2014.") (Finding of Fact 77). Defendants' deriding this clearly-articulated law from a unanimous

panel of the Court of Appeals as a mere "passing remark" (Defs.' Br. at 23) is inaccurate,[24] and their statement that the announcement of an imminent product withdrawal is the "sort of competition [] specifically allowed by the Second Circuit" rather than hard-switch conduct (Defs.' Br. at 19) is, respectfully, a flat misstatement of controlling law that they should correct. Defendants' attempts to reargue controlling law and elicit a decision from this Court that an announcement of imminent withdrawal is not "hard switch" conduct under Section 2 (*id.* at 19-26), after a unanimous panel of the Second Circuit decided otherwise, are improper and a waste of the parties' time and judicial resources. If Defendants wanted reargument, the place to seek it was in the Court of Appeals.

4. The Discontinuation Announcement and Other Associated Anticompetitive Conduct Are Not Protected Speech Under the First Amendment

Defendants' announcement of the withdrawal of Namenda IR was not protected commercial speech. Instead, it was anticompetitive conduct that was integral to its product hopping scheme and itself directly caused harm by coercing switches of prescriptions for IR to XR. Defendants claim that as a true statement of their intent it enjoys safe harbor, because only false, deceptive or misleading speech can constitute anticompetitive conduct. Defendants are wrong. First, Defendants' announcement was essentially false, deceptive and misleading because withdrawal of Namenda IR prior to generic entry was unlawful, and was enjoined by the district court (after it already "forced Alzheimer's patients who depend on memantine therapy to switch to XR"). *Namenda II*, 787 F.3d at 654. Indeed, the district court required that Defendants correct that announcement in its injunction. Second, the announcement was more akin to an

[24] Plaintiffs have a request *sub judice* that Defendants produce the unredacted court opinions from the injunctive actions, which Plaintiffs believe may undermine Defendants' assertions regarding the meaning of those opinions' language. Amended Letter Motion, ECF No. 60.

unlawful verbal act than protected commercial speech. Third, even if it were commercial speech, its employment as part of an anticompetitive scheme strips it of any First Amendment protection. Defendants' argument that the announcement of its planned discontinuation of Namenda IR was protected commercial speech under the First Amendment does not protect their scheme from antitrust scrutiny.

First, Defendants' announcement of the planned withdrawal of Namenda IR from the market may have been a true statement of intent, i.e., Forest did, in fact, plan to discontinue Namenda IR. However, the district court's injunction made clear that withdrawal from the market before generic entry was unlawful. Despite the fact that the announcement truthfully conveyed Defendants' anticompetitive intent, the announcement itself was unlawful, and caused as much, or more, harm, as a false statement.[25] The First Amendment does not provide protection for anticompetitive conduct, even if it may include a technically "true" statement. *See FTC v. Superior Court Trial Lawyers Ass'n*, 493 U.S. 411, 430-32 (1990) (holding that assigned counsel association's refusals to take new indigent cases was not shielded by First Amendment as it was an anticompetitive boycott); *Nat'l Soc. of Prof'l Eng'rs v. United States*, 435 U.S. 679, 699 (1978) (affirming ruling that a professional association's ban on competitive bidding violated the antitrust laws even though one means of carrying out the ban was through the publication of an ethical code).

[25] That a theater goer lit a match before truthfully yelling "fire" in order to clear out the theater in a panic would not render that communication protected speech. *See Schenck v. United States*, 249 U.S. 47, 52 (1919) (shouting "fire" in a crowded theater not protected under the First Amendment). Here, Defendants intended to cause an anticompetitive effect through their conduct in announcing withdrawal, and they did so.

Second, as the Second Circuit already found in *Namenda II*, the "truthful" announcement of withdrawal was "tantamount to withdrawal." 787 F.3d at 648.[26] It was, in essence, verbal anticompetitive conduct, and therefore lacks First Amendment protection.[27] Forest's announced discontinuance of Namenda IR effectuated a "hard switch" on the market and resulted in substantial substitution from Namenda IR to Namenda XR. Compl. ¶ 174. Indeed, the district court's injunction mandated that "'Defendants shall inform healthcare providers, pharmacists, patients, caregivers, and health plans of this injunction and the continued availability of Namenda IR[,]'" *Namenda II*, 787 F.3d at 649, which was necessary to counter the effect on the market from the announcement of withdrawal (as alleged in the Complaint, this withdrawal announcement caused an increase in switching from approximately 15% to approximately 50%). Compl. ¶ 185; *see also id.* ¶ 168 (Forest's C.E.O. admitted "'[I]f we do the hard switch and we've converted patients and caregivers to once-a-day therapy versus twice a day, it's very difficult for the generics then to reverse-commute back, at least with the existing Rxs.'"); *id.* ¶ 169 (Forest executive admitted "'anyone converted [to Namenda XR] is likely to stay converted'").

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[26] The district court had found a likelihood of success on not only the *attempted* monopolization claim brought by the NYAG, but also on the completed claim of monopolization. *See Namenda I*, 2014 U.S. Dist. LEXIS 172918, at *116.

[27] *See Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 514 (1972) ("It is well settled that First Amendment rights are not immunized from regulation when they are used as an integral part of conduct which violates a valid statute."); *Litton Sys., Inc. v. Am. Tel. & Tel. Co.*, 700 F.2d 785, 807 (2d Cir. 1983) (*Noerr Pennington* did not apply to private commercial activity of imposing and maintaining interface tariff, even though filed with FCC); *Carpet Grp. Int'l v. Oriental Rug Imps. Ass'n*, 256 F. Supp. 2d 249, 262 (D.N.J. 2003) (where such activity does 'not take place in the open political arena, where partisanship is the hallmark of decision making,' and 'can be more aptly characterized as commercial activity with a political impact,' the *Noerr-Pennington* doctrine does not apply"); *Welch v. Am. Psychoanalytic Ass'n*, 1986 U.S. Dist. LEXIS 27182, at * 22 ("If defendants' activities are later to be found to restrain trade, the First Amendment will not shield them.").

Third, as the court in *Abbott Laboratories v. Teva Pharmaceuticals USA, Inc. (In re TriCor Antitrust Litigation)*, 432 F. Supp. 2d 408, 424 (D. Del. 2006) ("*Tricor*") found with respect to a similar announcement, Defendants' coercive and illegal conduct could not be shielded under the First Amendment as "commercial speech." There, defendants argued that their truthful communication to the National Drug Data File that the old *TriCor* should be delisted was protected speech under the First Amendment. The court disagreed:

> As to the allegations regarding [National Drug Data File] code changes, Defendants also assert that the changes were commercial speech protected under the First Amendment…Even if the First Amendment applies, simply raising it as a talisman, as Defendants have done, is insufficient to provide immunity from antitrust scrutiny. The Supreme Court has addressed the issue of First Amendment protection from antitrust liability, stating that "First Amendment rights are not immunized from regulation when they are used as an integral part of conduct which violates a valid statute." *Cal Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 514, 92 S. Ct. 609, 30 L. Ed. 2d 642 (1972). Here, the changes in the NDDF code are alleged to be part of the Defendants' anticompetitive scheme, and those changes are an appropriate part of the circumstances to be considered in this case when evaluating Defendants' allegedly unlawful actions.

The three cases that Defendants rely upon provide them no safe harbor. In *MCI*, the challenged speech was the preannouncement of a lawful price; thus, at issue was a truthful statement about lawful conduct. *MCI Commc'ns Corp. v. Am. Tel. & Tel. Co.*, 708 F.2d 1081, 1129 (7th Cir. 1983). Here, it was the announcement of a product discontinuance, which specifically has been found to be an unlawful act; indeed it was enjoined, and the court required that the announcement itself be undone through a corrective announcement that the product would not be withdrawn prior to generic entry. In *Berkey Photo*, the speech at issue was typical marketing and promotional activities, and the court observed, "Advertising that emphasizes a product's strengths and minimizes its weaknesses does not, at least unless it amounts to deception, constitute anticompetitive conduct violative of § 2." 603 F.2d at 287-88. Similarly, in *United States Football League v. National Football League*, the speech at issue was typical

comparative advertising, including disseminating true, though unflattering, information about a competing product. 634 F. Supp. 1155, 1183 (S.D.N.Y. 1986). Each of these cases stands for the unremarkable proposition that advertising is not actionable under the antitrust law unless it is false, deceptive or misleading. Defendants' announcement of withdrawal of Namenda IR was not advertising.

Defendants' notice to the Centers for Medicare and Medicaid Services ("CMS") and request for CMS to remove Namenda IR from the Formulary Reference File ("FRF") similarly is not petitioning activity protected by the First Amendment under the *Noerr-Pennington* doctrine. While *Noerr-Pennington* offers immunity for petitioning activities, such activity can nevertheless be evidence of unlawful anticompetitive behavior. Even assuming that Defendants' requests to CMS were "petitioning" (a dubious assertion given that CMS is acting in a ministerial fashion with respect to its FRF),[28] "First Amendment rights are not immunized from regulation when they are used as an integral part of conduct which violates a valid statute." *Cal. Motor Transp. Co.*, 404 U.S. at 514. "First Amendment rights may not be used as the means or the pretext for achieving 'substantive evils' (*see NAACP v. Button*, 371 U.S. 415, 444) which the legislature has the power to control. Certainly the constitutionality of the antitrust laws is not open to debate." *Id.* at 515. As such, the First Amendment cannot be used as a shield to protect Defendants from antitrust liability for any of their unlawful anticompetitive conduct. "If the end result is unlawful, it matters not that the means used in violation may be lawful." *Id.* Much like

[28] "[T]he *Noerr-Pennington* doctrine is not applicable to conduct through which private parties seek to achieve anticompetitive aims by making representations to the government in circumstances where the government does not perform any independent review of the validity of the statements, does not make or issue any intervening judgment and instead acts in direct reliance on the private party's representations." *In re Buspirone Patent & Antitrust Litig.*, 185 F. Supp. 2d 363, 370 (S.D.N.Y. 2002) (citing *Litton Sys, Inc.*, 700 F.2d 785).

the *TriCor* defendants' requests for removal of the older TriCor formulation from the NDDF, Defendants' requests to CMS are actionable as part of an anticompetitive scheme. *See TriCor*, 432 F. Supp. 2d at 424.

E. Plaintiffs Have Sufficiently Alleged an Overarching Scheme to Monopolize

Plaintiffs have sufficiently alleged that Defendants' product hop and their agreements with their generic competitors to delay competition were all integral parts of an overarching scheme to unlawfully maintain Defendants' monopoly in the market for memantine hydrochloride. Compl. ¶¶ 244-250. Defendants argue that the claim fails because there was nothing unlawful about their product hop or their ANDA settlements and therefore their conduct when viewed in combination cannot give rise to an antitrust violation. Defs.' Br. at 61-62. But even if Defendants' product hop and reverse payment agreements were lawful (and they are not), the law is clear that where allegations of anticompetitive conduct "involves multiple acts, '[t]he character and effect of [the] conspiracy are not to be judged by dismembering it and viewing its separate parts, but only by looking at it as a whole.'" *Namenda II*, 787 F.3d at 654 (quoting *Cont'l Ore Co.*, 370 U.S. at 699 (internal quotation marks omitted)); *see also LePage's Inc. v. 3M*, 324 F.3d 141, 162 (3d Cir. 2003) (en banc) (when determining antitrust liability, "the courts must look to the monopolist's conduct taken as a whole rather than considering each aspect in isolation."). Plaintiffs' Complaint sufficiently alleges that the product hop and the settlement agreements were part of Defendants' overarching scheme to unlawfully maintain monopoly power. Defendants' cases are all inapposite as they principally relate to the combination of failed *claims* to support a new claim, rather than the combination of *facts* to support a single claim. *See, e.g., ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 280 (3d Cir. 2012) ("*linkLine* did no more than hold that two antitrust theories cannot be combined to form a new theory of antitrust liability."); *Universal Hosp. Servs. v. Hill-Rom Holdings, Inc.*, 2015 U.S. Dist. LEXIS

154154, at *16 (W.D. Tex. Oct. 15, 2015) ("[C]ourts have recognized that *Linkline* did not overrule the long established principles concerning the viability of claims alleging an overall scheme.") (internal citations omitted.); *In re Neurontin Antitrust Litig.*, 2009 U.S. Dist. LEXIS 77475, at *65-66 (D.N.J. Aug. 27, 2009) ("The distinction [between *linkLine* and a scheme case] is between analyzing individual acts or categories of anticompetitive conduct as contrasted with individual theories of liability derived from those acts. Here, Plaintiffs' legal theory itself advances a monopolization scheme claim.").

F. Plaintiffs Have Sufficiently Alleged Antitrust Injury

Plaintiffs have adequately alleged injury in fact under each theory of liability. As an initial matter, challenges to causation are so factually intensive that they are considered improper even at the *summary judgment* stage of litigation, much less during the motion to dismiss stage. Indeed, "[t]he issues of proximate causation and superseding cause involve application of law to fact, which is left to the factfinder, subject to limited review." *Exxon Co., USA v. Sofec, Inc.*, 517 U.S. 830, 840-41 (1996); *accord Am. Tissue, Inc. v. Donaldson, Lufkin & Jenrette Sec. Corp.*, 351 F. Supp. 2d 79, 91 (S.D.N.Y. 2004) ("[P]roximate causation generally remains an issue of fact for the jury.") (citation omitted). Pharmaceutical antitrust cases are no different. *See, e.g.*, *King Drug Co. of Florence, Inc.*, 702 F. Supp. 2d at 537 ("[A]llegations that absent the anticompetitive settlement agreements between [brand] and the [generics], [plaintiffs] would have been able to purchase generic[s] at significantly reduced prices…meet the pleading requirements for standing."); *In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517, 535 (D.N.J. 2004) (similar). Defendants' argument, therefore, that "Plaintiffs' but-for scenarios are purely speculative and cannot support a reasonable inference of causation" (Defs.' Br. at 41) is baseless.

Plaintiffs have not made naked, conclusory, or "purely speculative" assertions regarding Forest's actions. Rather, Plaintiffs have adequately pled causation and antitrust injury by

offering substantial and specific facts regarding multiple potential paths to lawful, earlier and unimpeded generic entry but for Forest's anticompetitive actions. *See* Compl. ¶¶ 129-142, 192, 221-231.

1. Plaintiffs Adequately Allege That the Product Hop Caused Antitrust Injury

Defendants suggest Plaintiffs suffered no injury because they did not pay "supra-competitive prices" for Namenda XR, as it was offered at a "5% discount off of the Namenda IR WAC price." Defs.' Br. at 31. This does not support a finding that Plaintiffs were not injured. Of course, while Defendants were offering a slight discount over Namenda IR to help cause prescriptions to switch, that short term price reduction pales in comparison to the cost reductions from entry of generic Namenda IR. Given the impediments to "reverse commuting" found in *Namenda I*, 2014 U.S. Dist. LEXIS 172918, at *68, that Defendants exploited with the switch, any short term savings are quickly eaten up when that prescription remains with Namenda XR after generic Namenda IR enters the market at a 90% discount (Compl. ¶ 46).[29]

Contrary to Defendants' bid for immunity under "antitrust injury" principles, product hopping schemes cause the very type of harm that constitutes quintessential antitrust injury: overcharges paid by direct purchasers for a product, the price of which is inflated by defendant's improper exclusion or suppression of generic competition. *See, e.g.*, *Meijer, Inc. v. Ferring B.V. (In re DDAVP Direct Purchaser Antitrust Litig.)*, 585 F.3d 677, 688 (2d Cir. 2009) ("[T]he plaintiffs are purchasers of the defendants' product who allege being forced to pay supra-competitive prices as a result of the defendants' anticompetitive conduct. Such an injury plainly

[29] Defendants also ignore that if there had been no Hatch-Waxman settlements and generics entered after the Hatch-Waxman litigation, as Plaintiff has alleged, the price of the Namenda IR available on the market would have been substantially lower than it actually was, and lower than the price of Namenda XR as well, since it would be subject to intense price competition. *See, e.g.*, Compl. ¶ 14.

is of the type the antitrust laws were intended to prevent.") (citation and internal quotation omitted); *In re Warfarin Antitrust Litig.*, 214 F.3d 395, 401 (3d Cir. 2000) (same). Impeding generic competition in the drug industry — and thereby minimizing substitution of lower priced generics for their expensive branded counterparts — is exclusionary conduct that inflicts classic antitrust injury (overcharges) on purchasers; it raises the generic competitors' costs to enter the market and impairs its market penetration. *Warfarin*, 214 F.3d at 401. As the Third Circuit noted, "[i]t is difficult to imagine a more formidable demonstration of antitrust injury." *Id.*; *see also La. Wholesale Drug Co. v. Hoechst Marion Roussel, Inc. (In re Cardizem CD Antitrust Litig.)*, 332 F.3d 896, 910 (6th Cir. 2003) ("Preventing [overcharge] was undoubtedly a *raison d'etre* of the Sherman Act when it was enacted in 1890.").

The *TriCor* court held that defendants' alleged conduct could have blocked competition and caused cognizable antitrust injury. *TriCor*, 432 F. Supp. 2d at 423. The *TriCor* defendants argued that because the generics "had not been prevented from marketing the formulations that were the subject of their ANDAs, i.e., the old TriCor formulations, they were not completely foreclosed, and were free to compete." *Id.* The court disagreed, explaining that to show that conduct has an anticompetitive effect, "it is not necessary that all competition be removed from the market. The test is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit." *Id.* at 422-23; *see also In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 64 F. Supp. 3d 665, 684-85 (E.D. Pa. 2014) ("If the anticompetitive effect of [the product hop] is proven, and it resulted in purchasers paying inflated prices, Plaintiffs could establish harm to competition itself.…Therefore, I find that Plaintiffs have pleaded sufficient facts to establish antitrust injury.").

As in *TriCor*, Defendants' product hop "severely restricted the ambit" of generic competition by using their announcement of withdrawal to cause doctors to switch prescriptions from Namenda IR to Namenda XR, thus limiting the number of prescriptions that could be subject to automatic AB-rated generic substitution when generic Namenda IR was finally launched. Schemes that foreclose lower priced competitors from the market, thereby allowing a monopolist to impose higher prices on purchasers without losing significant sales, are textbook examples of conduct that can — and must — be carefully scrutinized. *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 194 (3d Cir. 2005). "When the introduction of a new product by a monopolist prevents consumer choice, greater scrutiny is appropriate." *TriCor*, 432 F. Supp. 2d at 421.[30] Plaintiffs suffered overcharges when Forest used its monopoly power to impair the market for less-expensive generic memantine hydrochloride products. Antitrust law provides a remedy precisely for abuses of this type.

2. Plaintiffs Have Adequately Alleged That Defendants' Unlawful Extension of the Patent Caused Plaintiffs Injury

Beyond Defendants' product hop, it is undeniable that, but-for Defendants' reverse payment and market allocation agreements that illegally license after patent expiration (*see supra*, § III.A), generic competitors would have been able to launch their lower priced generic Namenda into the market *at the very latest* upon the expiration of the '703 Patent on April 11, 2015. It is worth noting that such a launch could not possibly be "at risk" because, again, the '703 patent would have already expired. And because no less than seven generic companies

[30] The fact that Forest is an alleged monopolist is highly significant. "[B]ehavior that otherwise might comply with the antitrust law may be impermissibly exclusionary when practiced by a monopolist." *Dentsply*, 399 F.3d at 187; *accord LePage's*, 324 F.3d at 151-52 ("[A] monopolist is not free to take certain actions that a company in a competitive . . . market may take"); *see also Microsoft*, 253 F.3d at 65 ("Judicial deference to product innovation, however, does not mean that a monopolist's product design decisions are per se lawful").

possessed FDA final approval for their respective products at that time (and earlier), the launch, would have caused aggressive price competition among the generics and the brand, and the generics quickly would have captured the majority of the memantine hydrochloride market, allowing Plaintiffs to purchase the product at a significantly lower cost. Compl. ¶¶ 4, 45-46, 50, 54, 133.

Moreover, since the settlement agreements [redacted] and since pediatric exclusivity did not apply to any ANDA filer in this case, the appropriate entry date in the but-for world would have been [redacted] (assuming Plaintiffs only proceed with the *Brulotte* claim).

3. Plaintiffs Have Adequately Alleged Antitrust Injury from the Reverse Payment Agreements

Plaintiffs allege that but for the anticompetitive contingent entry agreements at issue in this case, many of the first-filing generics would have launched their generic products earlier under one of the following circumstances: (a) after receiving FDA approval while the patent litigation or appeals were still pending (i.e., "at-risk"); (b) upon prevailing against Forest in the underlying patent litigation; (c) via procompetitive settlement agreements, i.e., *without* pay-for-delay or contingent launch provisions; or (d) at the very latest in April 2015 upon the expiration of the '703 patent. Compl. ¶ 14.

Courts have repeatedly held that a plaintiff can establish antitrust injury by alleging that the generic manufacturer would have launched at risk,[31] or under a license that provided for

[31] *See, e.g., In re Cardizem CD Antitrust Litig.*, 332 F.3d at 911 (finding antitrust injury because "a trier of fact may well find that the [brand's] $89 million payment renders incredible the defendants' claim that [the generic] would have refrained from marketing [during the patent litigation] simply because of its fear of infringement damages"); *Andrx Pharm. Inc. v. Biovail*

earlier generic entry. *See In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (3d Cir. 2012) ("[I]t is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise.") *rev'd on other grounds*, *Actavis*, 133 S. Ct. 2223; *In re Niaspan*, 42 F. Supp. 3d at 751-52 ("[A] reverse payment…is likely to induce the generic to agree to enter the market at a date later than that to which it would otherwise agree based solely on the estimated strength of its litigation position."); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 209-10 (E.D.N.Y. 2003) (theory that absent the reverse payment licensed generic entry date would have been earlier was not speculative).

G. Plaintiffs' Claims Are Not Time-Barred

Because "[t]he statute of limitations is an affirmative defense," dismissal "on statute of limitations grounds at the complaint stage 'is appropriate only if a complaint clearly shows the claim is out of time.'" *In re Crude Oil Commodity Futures Litig.*, 913 F. Supp. 2d 41, 58 (S.D.N.Y. 2012) (quoting *Harris v. City of New York*, 186 F.3d 243, 250 (2d Cir. 1999)); *see also BPP Ill., LLC v. Royal Bank of Scot. Grp. PLC*, 603 Fed. App'x. 57, 59 (2d Cir. 2015) ("[T]he statute of limitations is an affirmative defense, and a plaintiff is not required to plead, in a complaint, facts sufficient to overcome an affirmative defense.") (quotation marks omitted). Defendants cannot meet their heavy burden here as to any of Plaintiffs' claims.

Corp. Int'l, 256 F.3d 799, 813 (D.C. Cir. 2001) (reversing dismissal based on antitrust injury because a reasonable juror could conclude that but for the brand's $10 million quarterly payments, the generic *would have* entered the market); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 390 (D. Mass. 2013) (denying motion to dismiss in reverse payment action including at-risk launch theory of damages); *Biovail Corp. Int'l. v. Hoechst AG*, 49 F. Supp. 2d 750, 767-68 (D.N.J. 1999) (plaintiffs' allegations of injury were not too "speculative," despite defendants' argument that the generic would not have come to market at-risk).

1. Under *Berkey Photo*, a Purchaser's Cause of Action for Damages Accrues Each Time It Pays an Overcharge and a Purchaser May Satisfy the Conduct Prerequisite to Recovery by Pointing to Anticompetitive Actions Taken Before the Four Year Limitations Period.

In asking the Court to find that Plaintiffs' claims are barred by the statute of limitations, Defendants ignore controlling authority that a purchaser may assert claims for overcharges incurred within the limitations period regardless of whether the anticompetitive conduct occurred earlier. *See Klehr v. A.O. Smith Corp.*, 521 U.S. 179, 189 (1997); *Berkey Photo*, 603 F.2d at 296. As one district court recently noted, "[e]very court to have considered this issue in the pay-for-delay context has held that a new cause of action accrues to purchasers upon each overpriced sale of the drug." *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d at 746-47. Thus, Plaintiffs suffered injury — and a cause of action accrued — each time they purchased Namenda IR at an unlawfully inflated price, even if the conduct causing that price inflation occurred more than four years ago. *E.g.*, *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d at 237-39 (citing *Berkey Photo*).

In *Berkey Photo*, plaintiff claimed that it had been overcharged for its purchases of Kodak film and paper; Kodak argued (as Defendants do here), and the district court erroneously held, "that the cause of action of a purchaser seeking to recover an illegal overcharge accrues when the defendant engages in the anticompetitive conduct that is a prerequisite for suit." 603 F.2d at 295. The Second Circuit reversed, noting that "the purchaser's claim cannot accrue until it actually pays the overcharge," and that "a purchaser suing a monopolist for overcharges paid within the previous four years may satisfy the conduct prerequisite to recovery by pointing to anticompetitive actions taken before the limitations period." *Id.* at 295-96. The Court explained that:

> [A] purchaser…is not harmed until the monopolist actually exercises its illicit power to extract an excessive price…So long as a monopolist continues to use the

> power it has gained illicitly to overcharge its customers, it has no claim on the repose that a statute of limitations is intended to provide.[32]

Accordingly, since Plaintiffs' damage claims are limited to overcharges paid within four years of the complaints' filing, their claims are timely.

2. Defendants' Cases Do Not Support Dismissal of the Plaintiffs' Complaint on Statute of Limitations Grounds

Despite this case falling "clearly and squarely" under *Berkey Photo,* Defendants proffer citations from non-antitrust cases, brought by competitors rather than direct purchasers and/or are from outside this Circuit. Defs.' Br. at 62-65. Defendants primarily rely on *United States v. Grimm,* 738 F.3d 498 (2d Cir. 2013) and *In re Ciprofloxacin Hydrochloride,* 261 F. Supp. 2d 188. Defendants in *In re Aggrenox Antitrust Litigation* relied on these and other cases that Defendants reference here, and Judge Underhill wrote that "they do not examine the issue pertinent here of purchasers alleging ongoing overcharges." 94 F. Supp. 3d at 238.

IV. CONCLUSION

For the reasons sated above, Forest and Merz's motion to dismiss the Direct Purchaser Plaintiffs' Amended Complaint should be denied.

Dated: February 1, 2016

[32] *Id.* While Berkey's claims were brought under Section 2, the Court noted that its holding was consistent with the Supreme Court's analysis of when a cause of action accrues for a Section 1 conspiracy claim. *Id.* ("Thus, in this setting, as in 'the context of a continuing conspiracy to violate the antitrust laws…each time a plaintiff is injured by an act of the defendants a cause of action accrues to him to recover the damages caused by that act…[A]s to those damages, the statute of limitations runs from the commission of the act.'") (quoting *Zenith Radio Corp. v. Hazeltine Research,* 401 U.S. 321, 338 (1971)). The Court further observed that it "would undercut enforcement of the Sherman Act to hold that, if a monopolist merely retains its illicit market control for four years after its last anticompetitive action, it may charge an exorbitant price until its power is eviscerated in an appropriate suit for equitable relief." *Id.* at 296.

Respectfully Submitted:

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CERTIFICATE OF SERVICE

I hereby certify that on February 1, 2016, I electronically filed the above memorandum by CM/ECF system.

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